CENTRATEX- iron, sodium ascorbate, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, folic acid, cyanocobalamin, niacinamide, calcium pantothenate, zinc sulfate, magnesium sulfate, manganese sulfate, and cupric sulfate anhydrous capsule Centurion Labs, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Centratex Capsules

Capsules

Iron 106 mg, Sodium Ascorbate 200 mg, Thiamine 10 mg, Riboflavin 6 mg, Pyridoxine 5 mg, Folic Acid 1 mg, Cyanocobalamin 15 mcg, Niacinamide 30 mg, Pantothenic Acid 10 mg, Zinc 18.2 mg, Magnesium 6.9 mg

| Copper (Copper sulfate) | 0.8 mg |
|-------------------------------|--------|
| Manganese (Manganese Sulfate) | 1.3 mg |

A medical food, for use only under the direction and supervision of a licensed physician.

RX only

DESCRIPTION

Active Ingredients (Each capsule)

| 106 |
|----------|
| mg(Iron) |
| 200 mg |
| 10 mg |
| 6 mg |
| 5 mg |
| 1 mg |
| 15 mcg |
| 30 mg |
| 10 mg |
| 18.2 mg |
| 6.9 mg |
| 0.8 mg |
| 1.3 mg |
| |

Inactive Ingredients

Microcrystalline Cellulose, Silica, Magnesium Stearate, Gelatin Capsule

INDICATIONS

For the treatment of anemia due to lack of iron and low folate as in menorrhagia, pregnancy, puberty, excessive blood loss, and advanced age. Also for treatment of conditions where iron and vitamin C deficiency occur together, along with a poor intake or increased need for B-complex vitamins in chronic and acute illness, as well as cases of metabolic stress, and in periods of extended recovery.

CONTRAINDICATIONS

Centratex is contraindicated in patients with a known hypersensitivity to any of its ingredients. Iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, and hemolytic anemias. Folic acid may obscure signs and symptoms of pernicious anemia and is therefore a contraindication as well.

Warning

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately. Iron is toxic and has been shown to cause severe reactions in children including death.

Warning

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B-12 is deficient.

PRECAUTIONS

General

Folic acid in doses above 0.1 mg - 0.4 mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive.

PEDIATRIC USE

Safety and effectiveness in pediatric patients has not been established.

GERIATRIC USE

No clinical studies have been performed in patients over 65 to determine whether older persons respond differently from younger persons. Physicians should consider that elderly persons may have decreased hepatic, renal, or cardiac function.

ADVERSE REACTION

Allergic sensitizations have been reported following both oral and parenteral administration of folic acid. Gastrointestinal disturbances (anorexia, nausea, diarrhea, constipation) occur occasionally, but are usually mild and subside with continuation of therapy and physician encouragement. Although the absorption of iron is best when taken between meals, occasional G.I. disturbances may be controlled by giving Centratex shortly after meals.

DOSAGE AND ADMINISTRATION

Adults only: 1 capsule daily between meals, orally. Not recommended in children.

HOW SUPPLIED

Centratex is supplied as a natural gelatin capsule with tan speckled powder. Centratex is available in bottles of 100 (NDC 23359-100-10) and bottles of 30 (NDC 23359-100-30) Dispense in a tight, light resistant container as defined in the USP/NF with a child resistant closure. Store at room temperature between 15-30 degrees C (59-86 degrees F) Keep in a cool, dry place.

RX ONLY

Centurion Labs, LLC Birmingham, AL 35243

Rev. 8/17

PRINCIPAL DISPLAY PANEL - 30 Capsule Bottle Lable

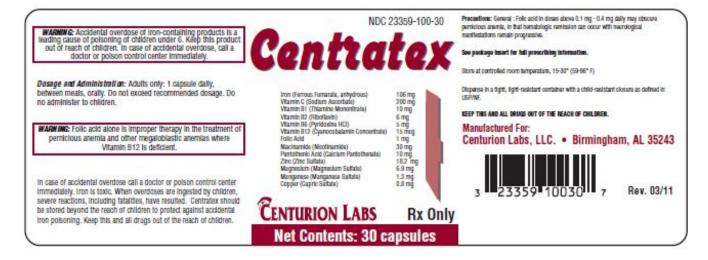
NDC 23359-100-30

Centratex

| Iron (Ferrous Fumarate, anhydrous | 106 mg |
|--|---------|
| Vitamin C (Sodium Ascorbate) | 200 mg |
| Vitamin B1 (Thiamine Mononitrate) | 10 mg |
| Vitamin B2 (Riboflavin) | 6 mg |
| Vitamin B6 (Pyridoxine HCl) | 5 mg |
| Vitamin B12 (Cyanocobalamin Concentrate) | 15 mcg |
| Folic Acid | 1 mg |
| Niacinamide (Nicotinamide) | 30 mg |
| Pantothenic Acid (Calcium Pantothenate) | 10 mg |
| Zinc (Zinc Sulfate) | 18.2 mg |
| Magnesium (Magnesium Sulfate) | 6.9 mg |
| Manganese (Manganese Sulfate) | 1.3 mg |
| Copper (Cupric Sulfate) | 0.8 mg |

CENTURION LABS Rx Only

Net Contents: 30 capsules

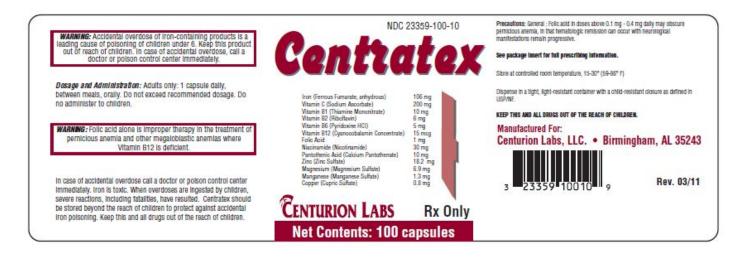


Centratex

| Iron (Ferrous Fumarate, anhydrous) | 106 mg |
|------------------------------------|---------|
| Vitamin C (Sodium Ascorbate) | 200 mg |
| Vitamin B1 (Thiamine Mononitrate) | 10 mg |
| Vitamin B2 (Riboflavin) | 6 mg |
| Vitamin B6 (Pyridoxine HCl) | 5 mg |
| Vitamin B12 (Cyanocobalamin | 15 mcg |
| Concentrate) | 13 mcg |
| Folic Acid | 1 mg |
| Niacinamide (Nicotinamide) | 30 mg |
| Pantothenic Acid (Calcium | 10 mg |
| Pantothenate) | 10 1110 |
| Zinc (Zinc Sulfate) | 18.2 mg |
| Magnesium (Magnesium Sulfate) | 6.9 mg |
| Manganese (Manganese Sulfate) | 1.3 mg |
| Copper (Copper Sulfate) | 0.8 mg |

CENTURION LABS Rx Only

Net Contents: 100 capsules



CENTRATEX

iron, sodium ascorbate, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, folic acid, cyanocobalamin, niacinamide, calcium pantothenate, zinc sulfate, magnesium sulfate, manganese sulfate, and cupric sulfate anhydrous capsule

| Product Information | | | |
|----------------------------|-------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:23359-100 |
| Route of Administration | ORAL | | |
| | | | |

| Active Ingredient/Active Moiety | | | |
|--|-----------------------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7) | IRON | 106 mg | |
| Sodium Ascorbate (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R) | ASCORBIC ACID | 200 mg | |
| THIAMINE MO NO NITRATE (UNII: 8 KO IO 49 19 X) (THIAMINE ION - UNII:4ABT0 J9 45J) | THIAMINE | 10 mg | |
| Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR) | Ribo fla vin | 6 mg | |
| Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z) | Pyridoxine Hydrochloride | 5 mg | |
| Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8) | Folic Acid | 1 mg | |
| Cyanocobalamin (UNII: P6 YC3EG204) (Cyanocobalamin - UNII:P6 YC3EG204) | Cyanocobalamin | 15 ug | |
| Niacinamide (UNII: 25X51I8RD4) (Niacinamide - UNII:25X51I8RD4) | Niacinamide | 30 mg | |
| Calcium Pantothenate (UNII: 568ET80C3D) (CALCIUM CATION - UNII:2M83C4R6ZB) | CALCIUM CATION | 10 mg | |
| Zinc Sulfate (UNII: 89DS0H96TB) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 18.2 mg | |
| $ \begin{tabular}{ll} \textbf{MAGNESIUM SULFATE, UNSPECIFIED} & (UNII: DE08037SAB) & (MAGNESIUM CATION - UNII: T6 V3LHY838) \\ \end{tabular} $ | MAGNESIUM SULFATE, UNSPECIFIED | 6.9 mg | |
| Manganese Sulfate (UNII: W00LYS4T26) (MANGANESE CATION (2+) - UNII:H6EP7W5457) | MANGANESE CATION (2+) | 1.3 mg | |
| Cupric Sulfate Anhydrous (UNII: KUW2Q3U1VV) (CUPRIC CATION - UNII:8CBV67279L) | CUPRIC CATION | 0.8 mg | |

| Inactive Ingredients | | | | |
|--|----------|--|--|--|
| Ingredient Name | Strength | | | |
| CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U) | | | | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | | | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | | | |
| GELATIN (UNII: 2G86QN327L) | | | | |

| Product Characteristics | | | |
|-------------------------|--|--------------|----------|
| Color | BROWN (clear with tan speckled powder) | Score | no score |
| Shape | CAPSULE | Size | 19 mm |
| Flavor | | Imprint Code | |
| Contains | | | |

| | Packaging | | | | |
|---|----------------|-------|--|-----------------------------|--------------------|
| ı | # Item Co | de | Package Description | Marketing Start Date | Marketing End Date |
| | 1 NDC:23359-10 | 00-10 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 06/14/2009 | |
| | 2 NDC:23359-10 | 00-30 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 06/14/2009 | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| Unapproved drug other | | 06/14/2009 | |
| | | | |

Labeler - Centurion Labs, LLC (016481957)

Registrant - Centurion Labs, LLC (016481957)

| Establishment | | | |
|--------------------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Contract Pharmacal Corporation | | 057795122 | manufacture(23359-100) |

Revised: 9/2019 Centurion Labs, LLC